WCG 2026 Trends & Insights

The challenges and opportunities shaping 2026.

As the clinical research landscape accelerates toward a new era, WCG remains committed to helping sponsors, CROs, sites, and investigators prepare for what lies ahead. 2026 is poised to bring both significant opportunity and increasing complexity, making readiness, not just innovation, a defining factor in research success.

Across the industry, site and investigator preparedness is becoming more strategic and more essential. Organizations are prioritizing workforce development, operational resilience, and standardized quality practices to meet rising study demands and increasingly sophisticated protocols. At the same time, participant experience is taking center stage. As expectations shift, trial teams are reimagining engagement, support, and communication to strengthen trust and improve retention across diverse populations.

Advanced therapeutics, particularly cell and gene therapies, are expected to expand rapidly, introducing new workflows, safety considerations, and regulatory requirements. Anticipating these needs is critical, as these modalities promise profound clinical benefit but require precision across every step of the development and delivery process.

Meanwhile, technology continues to transform clinical trials. Artificial intelligence and machine learning are transitioning from exploratory use to operational integration, offering the potential to enhance feasibility assessment, streamline workflows, and uncover opportunities that were previously out of reach.

The insights that follow take a deeper look at these trends, highlighting the signals that will shape 2026, the challenges that demand our attention, and the opportunities that will define the next chapter of clinical research. We invite you to explore these insights and join us in charting a path forward.

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Artificial Intelligence and Machine Learning in Clinical Trials

In the evolving landscape of clinical research, artificial intelligence (AI) and machine learning (ML) are now catalysts for transformation rather than adjuncts. According to the 2025 WCG CenterWatch AI Benchmarking Report, AI will significantly impact clinical research over the next five years.

As trial designs grow in complexity, participant recruitment and retention continue to challenge sponsors, and as data volumes surge, the role of AI/ML has moved into the operational and strategic core. At its heart is the capacity to shift from reactive monitoring to proactive prediction: models trained on historic site and participant performance, for example, can flag bottlenecks, enabling faster feasibility decisions and targeted site selection.

Evidence from industry sources shows that such techniques can reduce study timelines and enhance recruitment precision. Equally, generative AI and large language models are reshaping document creation, protocol review, and data anomaly detection, bringing a new dimension of augmented intelligence to teams.

Behind the promise lie critical imperatives: governance of bias in algorithms, transparency of model decision-making, and protection of participant privacy and data integrity. In fact, the WCG CenterWatch AI Benchmarking Report found that among the top barriers to AI adoption are ethical concerns and data and privacy issues.

In this light, 2026 will mark a convergence: sophisticated AI/ML tools blended with human oversight, integrated into every phase of the trial lifecycle, from design to endpoint analysis. For sponsors, CROs, sites, and regulators, understanding how to harness and govern AI/ML responsibly will not just determine efficiency gains but also shape the future of ethical, high-quality clinical research.

Creating Efficiencies with Emerging Technologies

Tyler Bye, director, Site Solutions & Product Strategy

The process of clinical research is built on years of progress and strict regulatory guidelines, ensuring the reliability and trustworthiness of research outcomes. In a world where technology is rapidly advancing, there is an understood desire for research to accelerate accordingly, while still upholding regulatory rigor and safeguarding participant protection and privacy. Emerging technologies, particularly those powered by artificial intelligence (AI), are transforming how we approach study design, participant recruitment, and overall study conduct.

One of the most impactful innovations is predictive modeling, which is reshaping how sponsors and CROs design the protocol and then proceed to select countries and sites. The ability to synthesize large amounts of data, guided by specific intention, provides years of experience and data points that can be used for highly specific needs.

By analyzing historical trial data, evaluating similar protocol designs and outcomes, and integrating demographic trends with disease prevalence, predictive algorithms can identify regions and site profiles most likely to attract the optimal participant population.

This data-driven approach not only improves recruitment precision but also informs strategies that align with expected site and participant burden — ensuring feasibility and reducing dropout rates. Of course this is still in theory, the execution of the study conduct still relies on skilled healthcare professionals.

Following protocol design, these efficiencies naturally extend into the regulatory review process, where advancements such as centralized IRB models and digital submission platforms are streamlining approvals. While the conduct of an IRB/IBC is dependent on the expertise of those on the review board, the process of getting the submission to the board is where continuous improvement can be obtained. Pre-populated fields and real-time feedback with automated compliance checks can help sponsors navigate regulatory pathways with greater speed and confidence.

Once a study is underway, the operational gains provided by integrated platforms and smart data systems minimize the need for manual data entry and re-keying, reducing errors and saving time. As we see more platform-level technologies, real-time data flows between applications create a continuous feedback loop, empowering study teams with actionable insights and enabling faster decision-making.

Enabling sites is a critical lever for success in every clinical trial. A persistent finding from the WCG 2025 Clinical Research Site Challenges Report is that the number of technologies and vendors required for a site's trials is the greatest driver of clinical trial complexity. With technology solutions only on the rise, the focus needs to be on relieving the administrative burden and identifying points of integration and interoperability to provide site staff with a streamlined process.

Emerging technologies aren't going anywhere. They're now a permanent part of our industry. It's up to us to use them to make research more efficient, all without sacrificing the rigorous standards and participant protections that matter the most. And in clinical research, it's vital to keep people involved. A "human-in-the-loop" approach ensures that technology supports, rather than replaces, the clinical wisdom and judgment professionals bring to the table.

Innovations and Ethical Challenges of Artificial Intelligence in Research: What to Watch for in 2026

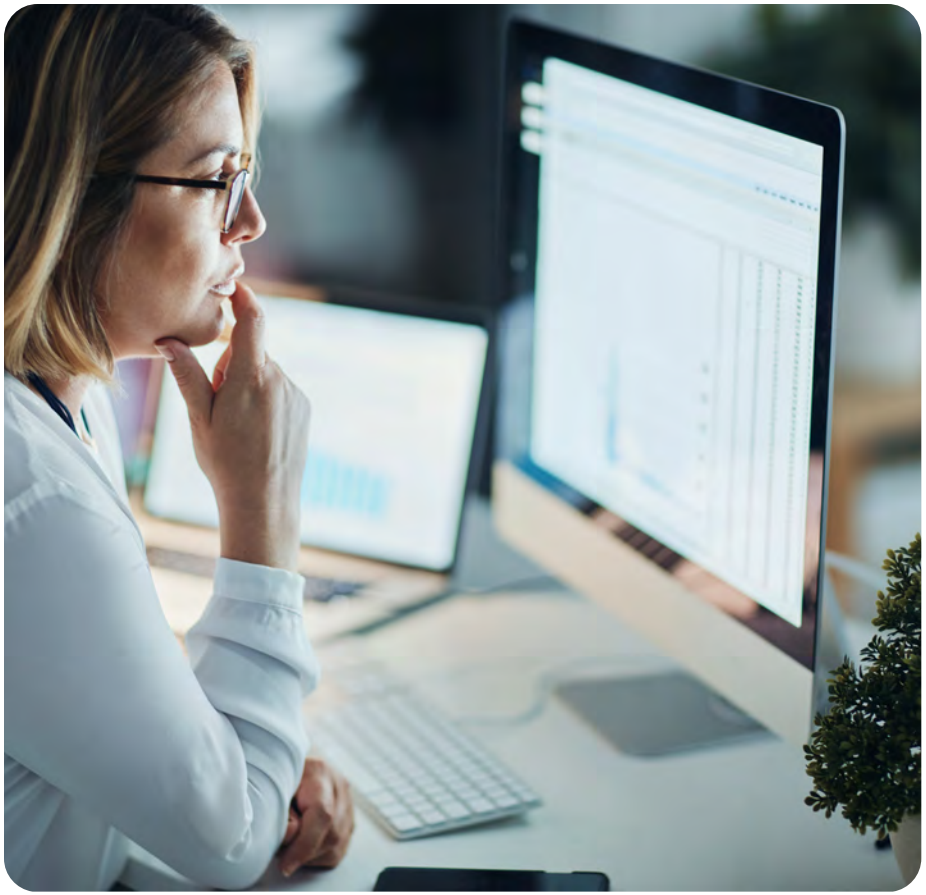
Donna Snyder, MD, MBE,
executive physician

The integration of artificial intelligence (AI) into research is rapidly transforming how studies are conducted, from participant recruitment to data collection and protocol review. As we look ahead to 2026, innovations in AI are poised to reshape research, but these advances are accompanied by significant ethical challenges that require thoughtful attention and ongoing oversight.

Innovations in AI Use for Research

Modern AI technologies leverage generative models, deep learning, and natural language processing to engage in complex, human-like tasks. These systems are increasingly being evaluated in research protocols, often as medical devices requiring regulatory oversight, or used to aid in the conduct of research by collecting patient-reported outcomes (PROs), maintaining electronic diaries, and facilitating participant recruitment by reviewing medical records to assess eligibility.

New innovations may include AI-assisted administration of informed consent, the use of AI bots to allow study staff to



query the protocol about specific protocol details, or pre-review of documents to ensure that appropriate regulatory elements are present. Furthermore, AI may be used to create essential research documents, such as protocols and informed consent forms, and to assess ethical issues or regulatory compliance. Many of these processes will increase efficiency and consistency in research overall.

Ethical and Regulatory Challenges

Some AI applications, such as those used to generate documents for human review, may not require Institutional Review Board (IRB) oversight, provided a human validates the content before use. However, when AI directly interacts with participants or influences study conduct, IRB review is essential to ensure that the rights and welfare of participants are protected. (A framework to help ensure participant protection and regulatory compliance in AI-enabled studies was developed by WCG and The MRCT Center's AI and Ethical Research project for IRBs and similar oversight bodies to navigate these new challenges.)

Protecting participant privacy and confidentiality remains a central concern, particularly if AI systems collect and process sensitive personal health information (PHI). The dynamic nature of AI means that data used to train and refine these technologies could change over time, necessitating ongoing oversight and validation.

Consent for both the use and reuse of participant data is critical. There is a risk of harm if AI provides inaccurate or incomplete information, especially in cases where it serves as the first point of contact for participants. Moreover, if AI replaces human review in tasks, like protocol assessment, there is concern that important details could be overlooked, potentially impacting participant safety and study validity.

AI holds tremendous potential to transform research, offering opportunities to enhance efficiency and accuracy. However, the use of AI in research introduces challenges related to participant privacy, data consent, and the necessity for ongoing oversight. Continued human involvement is essential to ensure ethical standards and participant safety as AI technologies become increasingly integrated into research practices.

AI and the Digital Future of Health in Latin America: A Sponsor's Opportunity

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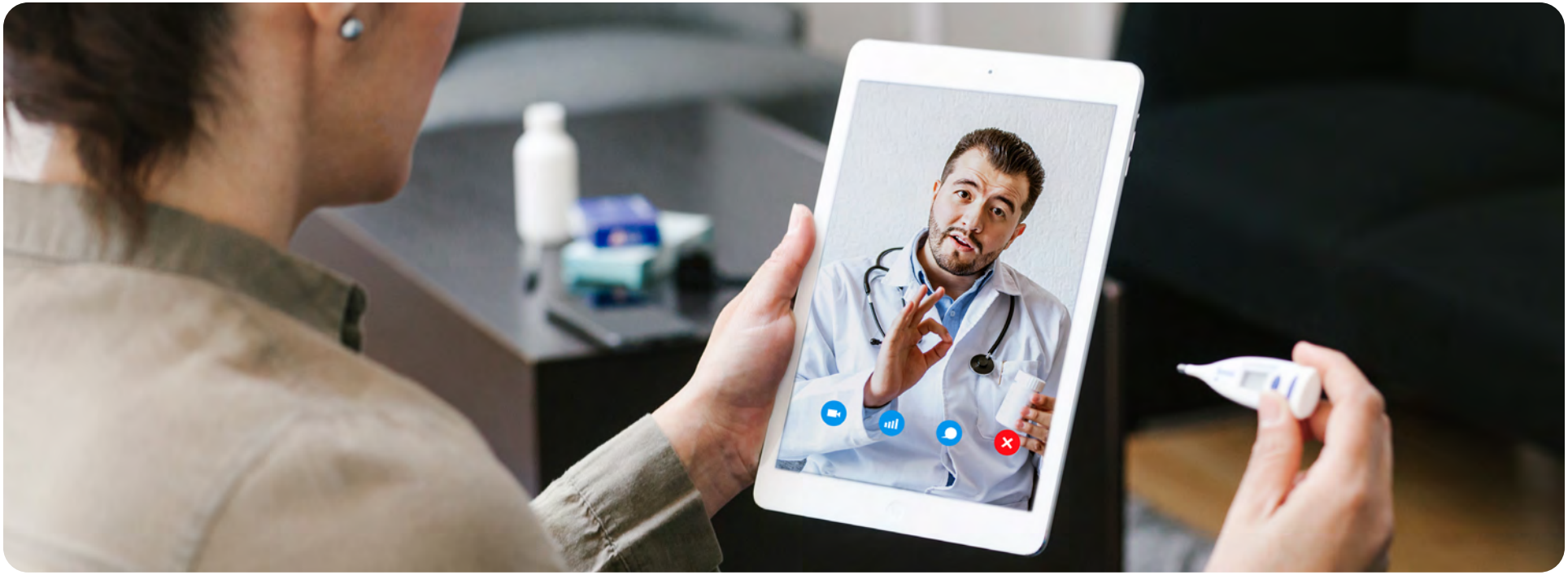
The way clinical trials are designed and delivered in Latin America is changing rapidly. Technology and innovation are breaking down traditional barriers, creating smarter, more inclusive approaches that expand access and improve representation. As the region becomes a strategic hub for global studies, sponsors that invest early in these trends will gain a powerful advantage.

Technology and Digital Health: Driving Equity and Access

In Latin America, the use of telemedicine platforms and wearable biosensors has demonstrated the potential to facilitate decentralized trials, support real-time data capture, and increase research accessibility for diverse populations. The surge in telehealth, especially in Ecuador and Mexico, demonstrates the region's readiness for digital solutions.[1]



Wearables and remote monitoring tools enable real-time data collection and flexibility, allowing patients to participate without the burden of travel, expanding geographic reach, improving retention, and enhancing data diversity[2].

AI-Enabled Patient and Site Matching: Smarter, Faster Research

Latin America has long faced challenges in connecting patients to clinical trials due to fragmented health records and limited access, particularly in rural and underserved regions[3]. Artificial intelligence (AI) is transforming this landscape by enabling smarter patient identification. Advanced AI systems, incorporating natural language processing and computer vision, are now extracting insights from unstructured sources such as clinical notes and pathology reports, streamlining pre-screening tasks for research coordinators and CROs[4]. "Predictive analytics then enable clinicians to identify patients most likely to benefit from specific therapies, minimizing the trial-and-error approach that can characterize traditional treatments"[5]. AI is set to revolutionize clinical research by 2026, offering new solutions for recruitment, data analysis, and participant engagement.[6]

Regulatory Modernization Paves the Way

Regulatory authorities such as ANVISA (Brazil) and COFEPRIS (Mexico) are moving swiftly to update frameworks supporting ethical AI use, patient privacy, and streamlined approvals. Their ongoing modernization efforts signal greater cross-border collaboration and alignment.[7] By 2026, expect regulatory harmonization to further open Latin America to multinational investment and larger, more inclusive studies leveraging the full power of AI and digital innovation.[8]

AI and digital health are not just incremental improvements; they are transformational forces for Latin American clinical research. Enhanced by AI, clinical workflows are becoming more efficient, while updated regulatory frameworks from ANVISA and COFEPRIS are ensuring ethical integration and robust data protection. For sponsors, this is a pivotal moment to invest in smarter, more inclusive research.

RELATED RESOURCES

- **WEBINAR:** Framework for AI Adoption in Clinical Trials: A Case Study Perspective
- **PODCAST:** AI in Clinical Trials: Unlocking the Potential
- **PODCAST:** Harnessing Generative AI in Clinical Research
- **REPORT:** WCG CenterWatch 2025 AI Benchmarking Report

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Site Readiness, Capacity, and Investigator Enablement

Clinical trial success rests fundamentally on the readiness, capability, and engagement of the sites and investigators executing the work. Yet the past several years have exposed growing strains: complex protocols, budget reductions, and multiple technology platforms contributing to increased administrative burden, mounting delays, and variability in performance. According to WCG's 2025 Clinical Research Site Challenges Report, 45% of sites said these persistent challenges are impacting their ability to participate in new studies.

In 2026, site and investigator readiness must be reframed not as a preparatory phase but as a continuous operational asset. This framework encompasses the processes, infrastructure (e.g., data capture systems), trained coordinators, motivated investigators, alignment on roles, realistic timelines, and shared expectations. It also means enabling sites with data-driven benchmarking, onboarding support, and streamlined start-up workflows.

As the industry moves toward fewer but more tightly run trials, often in highly specialized or decentralized settings, readiness becomes a key differentiator. Investing early in investigator engagement, measuring site performance, using predictive analytics for site activation, and designing protocols with site burden in mind will separate delays from acceleration.

For sponsors, CROs, and sites, the imperative is to build dynamic ecosystems of readiness where investigator networks are scalable, site engagement is embedded, and turnaround from selection to activation becomes faster and more predictable. 2026 will be the year when site readiness shifts from reactive troubleshooting to proactive optimization.

Preparing for the Future – Tackling Funding, Staffing, and Complexity Challenges at Clinical Research Sites in 2026

Sandy Smith, RN, MSN, AOCN, senior vice president, Clinical Solutions & Strategic Partnering

Clinical research sites are expected to face challenges in 2026 similar to those experienced last year. The turbulence that defined 2025 led many organizations to reassess their research strategies, particularly as federal funding was either at risk or significantly reduced. In response to shifting or canceled grants, changes in government contracts, potential adjustments to indirect rates, endowment tax revisions, and significant proposed cuts to Federal Medicaid spending, institutions evaluated three main strategies: (1) expanding the number of industry-sponsored trials, with some aiming for increases of 40% or more[1]; (2) establishing strategic partnerships; and (3) pursuing innovative and alternative funding sources. Some resounding themes from sites are a commitment to continuing research as a core of their mission, a commitment to patient care, and the advancement of science.

Despite these challenges, the trajectory of scientific advancement within clinical research is set to accelerate, driven by the integration of advanced technologies and innovative methodologies. Artificial intelligence (AI) and data analytics will be increasingly leveraged to enhance patient identification and optimize trial design. Within clinical trials, there will be a sustained emphasis on the use of gene editing technologies, real-world evidence, and precision medicine, resulting in trials that are progressively tailored to individualized profiles. The momentum observed in early-phase trials in recent years will persist, with numerous studies anticipated to progress into later phases. Oncology's dominance will remain, as will the continued rise in metabolic/endocrinology.

The advancements in science will continue to contribute to clinical trial complexity, placing a significant strain on research sites[2]. This complexity is driven by more intricate protocols, the integration of advanced technologies, a greater number of procedures and endpoints, expanded data collection, and longer trial duration. These factors collectively contribute to longer start-up times and operational challenges[3,4]. Research sites will need to be

resilient and committed to identifying new approaches to expedite trial activation and delivery.

Over the past years, research sites have faced persistent staffing challenges, primarily among clinical research coordinators (CRCs) and regulatory staff. In 2025, these difficulties expanded to the scientific workforce, exacerbated by threats to federal funding. Ongoing concerns will continue in 2026 with a shrinking talent pool within the clinical research workforce and intensifying demands on existing staff, impacting recruitment of new talent, and potentially leading to higher burnout and turnover. Contributing factors to these workforce issues include pandemic-related fatigue, poor work-life balance, declining public trust, and increasing clinical trial volume, which is currently outpacing available personnel. These workforce constraints may directly impede the pace of innovation and hinder the strategic direction of many research institutions.

One key win for research participants in 2026 is the increase in the tax-reporting threshold for participant stipends to $2,000 annually, effective Jan. 1, 2026[5]. Under the One Big Beautiful Bill Act (OBBBA), passed in 2025, research sites will no longer be required to collect W-9 forms for payments under $2,000, thereby reducing some of the administrative workload. The increase in the reporting threshold does not completely resolve the issue for participants relying on social welfare programs, as they remain obligated to report any income received, which could still affect their benefits eligibility. Advocacy will continue to exclude all clinical trial participants from taxable income, reducing this barrier to research participation.

Clinical research sites in 2026 will face ongoing funding challenges, increased trial complexity, and workforce shortages, requiring adaptability and innovation to sustain research and advance ongoing scientific progress.

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Tips to Improve Site Start-Up Timelines and Expedite Study Activation

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Stephanie Held, associate director, Coverage Analysis

Jody Ingebritsen-Howe, director, Contracts & Budgets

Clinical trial complexity continues to rise, and as sites and sponsors frequently report, study start-up remains a persistent challenge. The more complex a trial, the greater its potential impact on timelines for launching research. To optimize start-up, it is essential to address two primary drivers:

1. The quality and alignment of core component parts.
2. The presence and extent of "white space" — those gaps between and within active tasks that introduce delays.

Foundational Component Alignment — Starting with Medicare Coverage Analysis

At the heart of compliant and efficient study start-up is a comprehensive Medicare Coverage Analysis (MCA). A high-quality MCA sets the foundation for subsequent budget creation and seamless integration into Clinical Trial Management Systems (CTMS). While MCA itself is a relatively small part of the overall timeline, its true impact lies in how well it informs and supports other critical start-up components.

- A well-executed MCA enables accurate, transparent budgeting.
- A robust budget leads to faster and smoother contract negotiations.
- Together, a strong MCA and budget facilitate efficient CTMS or site management system build-out, further streamlining initiation.
- Ensuring each component is done correctly, and each properly informs and supports the next, is essential for quality and speed.

Reducing the "White Space"

Another lever for increasing efficiency and speeding up the start-up process is reducing unnecessary "white space."

"White space" refers to delays arising in the hand-offs, reviews, and approvals between key start-up activities. It's important to acknowledge that not all white space is detrimental; many such intervals safeguard essential approvals and coordination. Yet, when these pauses exist "just because it's always been done this way," they merit systematic review.

- For example, requiring redundant reviews or excessive sign-offs slows progress and can be streamlined.

> "Efficient study start-up isn't just about speeding up isolated steps, but creating a smarter, interconnected process."

- Investigating and understanding the rationale for each gap allows targeted solutions — clear documentation, simplified approval pathways, and well-defined negotiation parameters — to minimize interruptions.

Efficient start-up isn't just about speeding up isolated steps, but creating a smarter, interconnected process. By combining intentional configuration of systems like CTMS, enabling real-time tracking, integrated analytics, and proactive monitoring, with purposeful investigation of workflow bottlenecks, research teams can address both the quality of component parts and the space between them.

Ultimately, the optimal approach to accelerating study start-up is twofold:

- Ensure that each foundational component (such as MCA, budget, and CTMS) is executed with quality and informs the other components.
- Actively minimize unnecessary delays between and within these parts.

The result? Faster, smarter initiation; compliant and transparent workflows; and empowered teams positioned to deliver impactful results — on time, every time.

Building Infrastructure: Site Operational Maturity and Continuous Improvement

Trevor J. Cole, BS, MBA-HCM, CCRC, PMP, RN, program director, Clinical Solutions & Partnering

In 2026, the drive toward operational maturity at clinical research sites is emerging as a key trend shaping industry quality and efficacy. Site infrastructure — comprised of people, processes, and technology — must be purpose-built to support each organization's unique mission and growth objectives. This evolution in maturity is underscored by a strategic focus on quality management and continuous improvement.

A quality-driven culture forms the foundation of robust infrastructure, enabling teams to address issues collaboratively and align on shared goals. Leadership commitment is essential, with resources directed toward establishing and maintaining quality-first principles across all operational levels.

Operational maturity relies on clear, fit-for-purpose policies and procedures. Standard operating procedures (SOPs) should be adapted to site-specific needs, promoting consistency and reducing risk. Comprehensive training is equally important, with organizations investing in staff education to ensure that personnel are qualified, roles are clearly delineated, and opportunities for professional development are ongoing.

Risk management is gaining momentum, with forward-thinking sites adopting risk-proportionate strategies to anticipate and mitigate challenges related to participant safety, data integrity, and regulatory compliance. Proactive identification and evaluation of potential risks are integrated into operational protocols, driving early intervention and continual monitoring.

Issue management and corrective and preventive action (CAPA) frameworks are becoming standard practice, enabling sites to respond decisively to challenges, investigate root causes, and implement effective solutions. Continuous improvement is fueled by robust knowledge management processes, the systematic capture and sharing of lessons learned, and transparent communication of performance metrics throughout teams.

Furthermore, sites are increasingly engaging their local communities and trial participants, recognizing their integral role as stakeholders. Community involvement fosters trust, enhances relevance, and ensures research initiatives align with population needs.

Sites that embrace operational maturity will demonstrate resilience and adaptability, deliver higher quality research outcomes, and build lasting connections with participants and communities. This trend will accelerate the transition to more sophisticated, patient-centric models, positioning sites for success in the evolving clinical research landscape.

Strategies for Ensuring Site Readiness During Clinical Trial Delays

Miranda Olson, manager, Site Services, WCG Site Network

Site readiness involves several sponsor-directed activities that must be completed at the site level before enrollment starts, and a delay in one component of the process can cascade into further setbacks for sites. WCG's 2025 Clinical Research Site Challenges Report reveals that 31% of independent research sites and physician practices consider trial delays and cancellations a major issue impacting their operations, and 27% of those sites have already faced industry-sponsored trial pauses or cancellations. An additional 24% are concerned about future cuts, highlighting the ongoing uncertainty amidst industry shifts to new therapeutic areas, such as GLP-1s.

The additional challenge of trial complexity further complicates the ability for sites to easily pivot when

presented with a trial delay. More exclusionary protocols require extensive time dedicated to identifying qualified potential participants, staff training, and may potentially demand specialized staff involvement.

Delays in study start-up require sites to refocus on activities that best serve their patients and business needs, especially as these sites may have more limited resources and budgets. When those resources pivot, the prepared operational flow of the trial is disrupted, resulting in impacts to future site readiness and risking further study delays.

Delays in study timelines will likely continue in 2026, as they have in previous years. However, sites and sponsors can be better prepared to meet the challenges that result and avoid cascading issues that affect site readiness.

> Delays in study start-up require sites to focus on activities that best serve their patients and business needs."

Sponsor Recommendations

- Proactively communicate delays and disruptions to site study teams to avoid last-minute strain on study site staff and participants. Include additional information, such as reasons for delay and updated timelines, so that sites may adjust appropriately.
- Proactively provide sites with resources to support a successful study and assist with the additional workload caused by study delays.

Site Recommendations

- Openly communicate challenges that study delays present to your site and how these challenges affect site readiness.
- Ensure sufficient staffing is in place and establish adaptable processes that can accommodate changing trial timelines and demands.

Addressing study delays, challenges, and support needs can proactively mitigate future study delays or challenges. Most importantly, consistent communication and collaboration between sponsors and sites can facilitate smoother operations and patient interactions, thus protecting the clinical trial experience for participants.

Complexity Impacts Capacity: Turning Challenges into Collaborative Solutions

Trevor J. Cole, BS, MBA-HCM, CCRC, PMP, RN, program director, Clinical Solutions & Partnering

WCG's 2025 Clinical Research Site Challenges Report, which surveyed over 600 global research sites, revealed a striking reality: 35% of sites cite "complexity of clinical trials" as their top challenge.

This complexity is not monolithic; it spans protocol design, operational requirements, technology integration, and the ripple effect of amendments. As trials grow more intricate, site capacity is stretched thin, making collaboration and proactive planning essential.

Why Complexity Matters

Modern trial designs (e.g., adaptive, platform, umbrella) pack multiple objectives into a single protocol. Since 2015, Phase

III trials have seen a 42% increase in required procedures and a 37% rise in endpoints. Nearly one-third of collected data consists of non-core procedures, adding burden without supporting the primary endpoints[1].

Sites must advocate for streamlined protocols and early involvement in study design. In fact, 47% of sites say simplifying protocol complexity is vital for operational viability[2]. Every additional procedure, amendment, or technology layer can strain site resources, making collaboration and proportionality critical.

Could ICH E6(R3) Provide a Framework for Managing Complexity?

The updated guidelines emphasize Quality by Design (QbD) and Risk-Based Quality Management (RBQM), principles that align with supporting today's challenges:

- Quality by Design: Identifying Critical-to-Quality (CtQ) factors early can support the avoidance of unnecessary complexity.
- Risk-Proportionate Oversight: Focusing on scaling monitoring (central and traditional) and processes to the actual risk for a given study and sites can drive actions that are truly value-added to ensure quality.
- Data Governance: Strengthening the support and management of critical data along its flow, ensuring audit trails and system validations can maintain integrity.
- Proportionality: Applying a holistic fit-for-purpose approach to reduce burden while safeguarding quality can drive focus on what matters most to study success.

Dimensions of Complexity and Site Considerations

Protocol Complexity

- Embed operational feasibility reviews before finalizing protocols or taking on sponsor studies.
- Advocate for the elimination of non-core procedures that do not support primary endpoints or may cause participant and site burden.

Technology & Service Providers

- With the proliferation of technologies and 79% of sites reporting being the primary contact for tech issues, sponsors should prioritize integrated platforms and robust technical support, which over half of sites rank as a top improvement area[3].
- Sites can advocate for utilization of their systems when appropriate but should be ready to provide robust qualification and validation of those systems, ensuring they are fit-for-purpose.

People Hours & Logistics

- Increased procedures mean more staffing and resource needs. Sites must plan for increased personnel hours and logistical complexity, balancing quality, budget, and timelines. Operational capacity tools can support the awareness of capacity before making any study commitments.

Significant Amendments

- Phase III trials now average 3.5 substantial amendments, up from 2.3 a decade ago. Each amendment triggers rework: revised budgets, contracts, consents, and retraining.
- Sites should establish amendment response protocols and advocate for sponsor transparency to minimize disruption.

Data Governance

- Sites and sponsors must collaborate to streamline data collection, focusing on core endpoints and strengthening governance to ensure data integrity.

Complexity is inevitable, but unnecessary burden is not. By fostering reciprocal engagement, advocating for operational feasibility, and leveraging ICH E6(R3) principles, sites can preserve capacity and elevate quality, turning complexity into an opportunity for innovation.

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RELATED RESOURCES

- **REPORT:** 2025 Clinical Research Site Challenges Report
- **WEBINAR:** Strengthening Site Relationships in Global Clinical Trials
- **WEBINAR:** Research Resilience: Empowering Sites in Uncertain Times
- **WEBINAR:** Accelerating Site Activation: Best Practices for Optimizing CTMS Study Builds

Participant Experience, Engagement & Retention

Behind every clinical trial is a human story, a person, a family, an expectation of hope, and risk. Elevating the participant experience is not only a moral imperative but a strategic one: trials that center on the participant tend to enroll more efficiently, retain better, and yield higher-quality data. In 2026, participant experience must be considered holistically.

Consider this: According to a 2024 report from the Tufts Center for the Study of Drug Development, burden for participants in clinical trials is rising, especially in non-oncology studies.

As a result, the era of participant-centric design must mature into the era of participant-driven research, where protocols are designed *with* not just *for* participants, and where technology enables rather than replaces human connection. Data shows that participants increasingly come to trials informed, connected, and expectation-driven.

Participant experience in 2026 will distinguish trials, those that deliver merely to protocol and those that deliver both science and humanity. For sponsors, CROs, and sites, embedding experience-led design will drive better outcomes, deeper trust, and lasting value for participants and the broader ecosystem.

Improving Participant Experience: What is Preventing Time and Effort Payments to Participants?

Kelly FitzGerald, PhD, executive IRB chair & vice president of IBC Affairs, IRB Operations

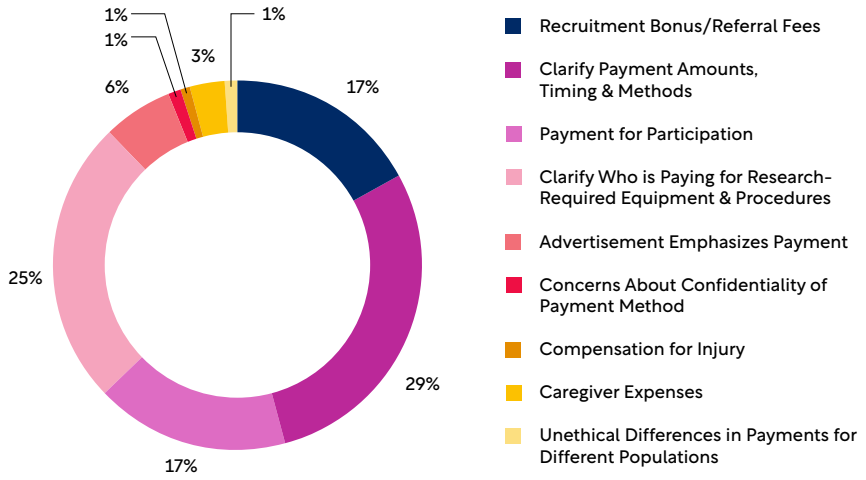
Delays in clinical trial enrollment and failures in retention are often more costly than participant payment budgets. Why don't sponsors compensate participants for their time and effort? WCG dug into our data to try to understand the impediments to using time and effort compensation as a tool for increasing enrollment and retention in clinical trials and to explore the role of the Institutional Review Board (IRB). Participant compensation is more than a budget line item. It touches on fairness, undue influence, equity, and transparency.

WCG analysis of informed consent forms revealed that 95% of studies do not offer compensation beyond basic reimbursement, meaning participants are typically only reimbursed for direct expenses, like travel or parking.

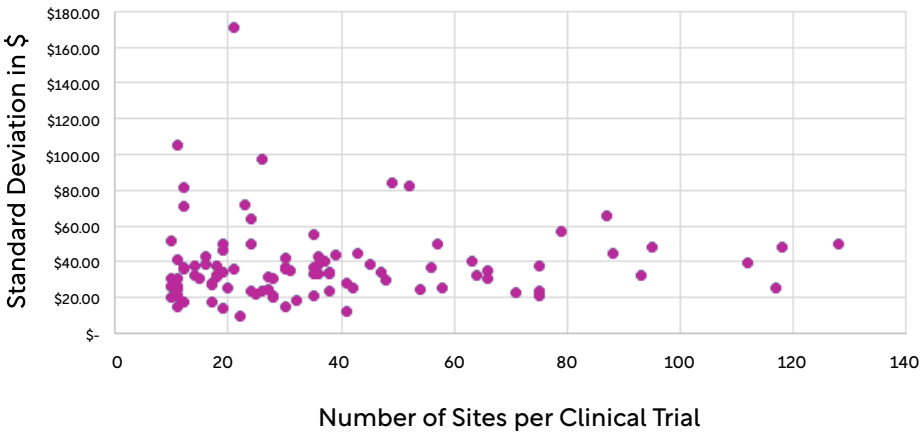
Then, WCG analyzed nearly 25,000 IRB records of conditional approvals and deferrals from convened IRB meetings where payment-related questions were raised. This analysis offers a rare glimpse into how institutional review boards interact with sites regarding payment issues.

WCG's analysis found 77 instances of payment-related issues that were specifically called out in board communications to sites. WCG categorized the board's payment-related questions into themes. The most frequent questions (29%) focused on clarifying timing, amounts, or payment methods, often due to vague or contradictory language in consent forms. Another 25% asked who paid for research-required equipment or procedures, especially in oncology or medical device trials, where financial determinations about clinical care versus research can be confusing.

Smaller portions included questions about caregiver expenses or payments, as well as ethically problematic payment differences between participant groups. One notable case involved a proposed payment scheme that compensated people with housing more generously than those without, raising serious concerns about fairness. In no case did the IRB have issue with the amount of payment being too high.



IRB Concerns Involving Payment 2021 - 2025



Standard Deviation of Average Compensation for Sites on the Same Clinical Trial

Independent IRBs and Site-Level Variation

As an independent IRB, WCG is positioned to examine compensation differences across sites in multi-site clinical trials. The variation in compensation across sites was striking. When site payments for a given clinical trial were analyzed, standard deviations in participant compensation ranged from $9 to $170.

This means a participant at one site might receive $25, while someone at another site enrolled in the exact same study might receive $150. These discrepancies raise important questions, including whether participants are being treated equitably across the study, whether local costs of living justify differences, and whether institutional policies and constraints inadvertently lead to unjust payments.

Sponsors, sites, and IRBs should be aligned on the benefits of equitable treatment, increased participant enrollment, engagement, and retention in clinical trials. Paying participants for their time and effort is ethical, and IRBs approve of it. The hope is 2026 will bring new opportunities for WCG to partner with institutions and sponsors to remove barriers to paying participants for time and effort.

Participant Experience, Engagement, and Retention: Optimizing the Human Side of Clinical Trials

Sharad Adekar, MD, PhD, CIP, medical chair lead, IRB Operations

Clinical trials are the backbone of medical innovation yet maintaining participant engagement and minimizing dropout rates remain persistent challenges. With dropout rates reaching as high as 30% in some studies[1], sponsors and research sites are increasingly recognizing the importance of optimizing the human side of trials not just as a necessity, but as a competitive advantage. A participant-centric approach is essential for successful recruitment, retention, and long-term involvement, especially in complex and lengthy studies such as those for cell and gene therapies.

Strategies for Enhancing Engagement

Engagement goes beyond mere participation; it involves cultivating a sense of connection and purpose among trial participants[2]. To achieve this, sponsors and sites need to employ a variety of innovative strategies[3]:

- Participant-Centric Trial Design: Involving participants and participant advocacy groups from the start for input into study design, subject materials, consenting process, and communication strategies ensures that trials are more aligned with their real-world needs and challenges. This helps to gain valuable insights into participant priorities, language, and concerns, ultimately enhancing trust and relevance. This teamwork makes study documents easier to understand and ensures participants feel informed and empowered throughout the trial.
- Personalized Communication: Tailoring information to each participant's needs and preferences helps clarify expectations, reduce anxiety, and create a supportive environment.
- Digital Tools and Remote Monitoring: Leveraging technology such as patient portals, mobile applications, artificial intelligence, wearable devices, virtual visits, and electronic Patient-Reported Outcomes (ePRO) questionnaires enable participants to interact with the study team more easily, reduce burdens, and track their

own progress. These tools also facilitate timely reminders, feedback, and support, reducing dropout rates.

- Flexible Scheduling and Locations: Allowing participants to choose appointment times and attend visits at convenient locations lessens disruption to their daily lives.
- Transportation: Sponsors and sites should proactively assess and mitigate obstacles to participation, including transportation and financial limitations, by providing tailored support where appropriate.
- Feedback Mechanisms: Requesting participant feedback on their experiences and acting on their suggestions demonstrates respect and a commitment to continuous improvement.

Building Trust and Sustaining Retention

Trust is the foundation of a successful participant-site relationship. Participants must feel confident that their interests are protected, and their voices are heard. Transparency in trial objectives, procedures, and potential risks is key to building this trust. Regular updates, open lines of communication, and prompt responses to concerns all contribute to a positive trial experience.

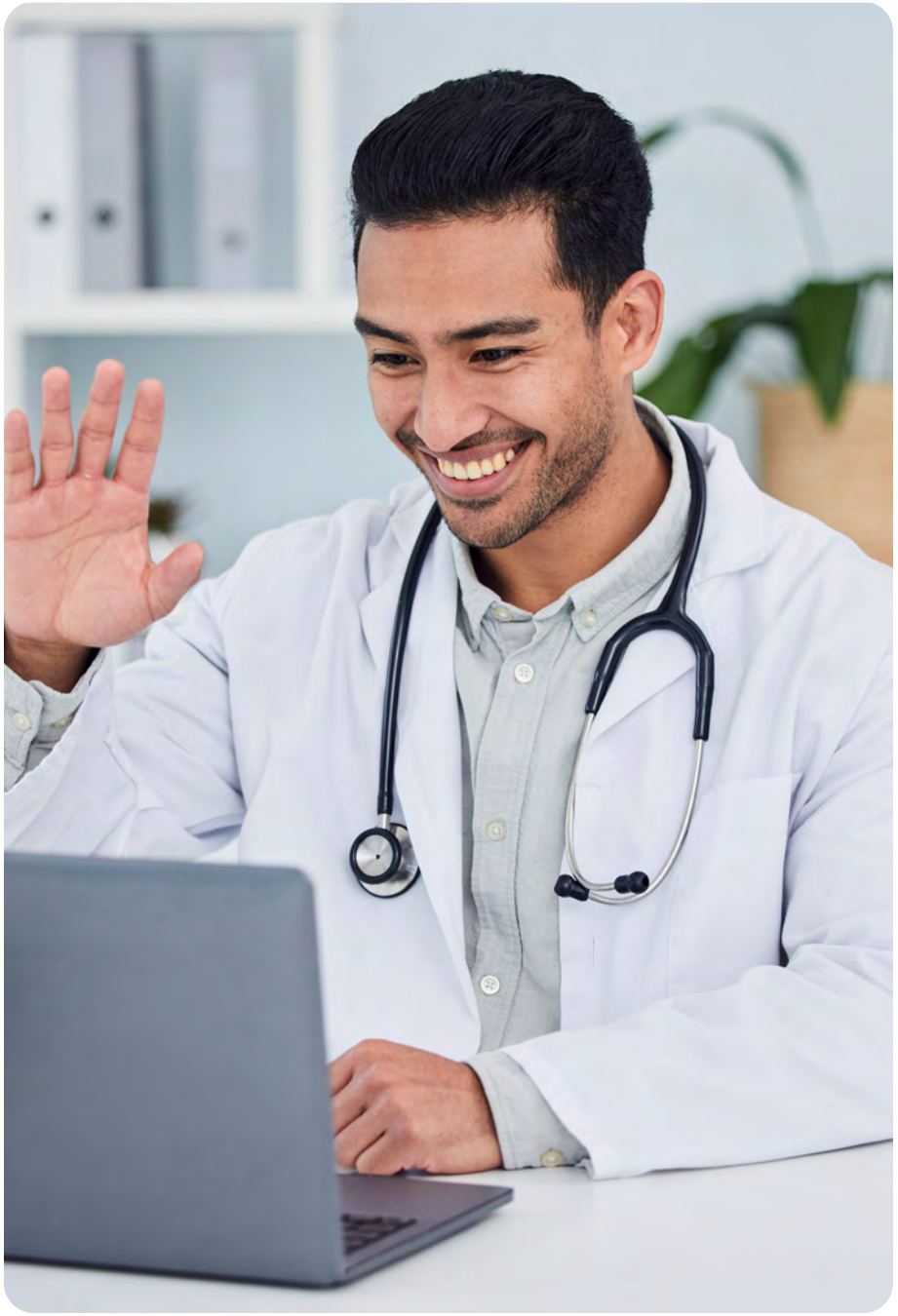
Retention is particularly significant in cell and gene therapy research, where long-term follow-up over several years is required after a single intervention. Engaging participants and their families as collaborative partners and involving them as research ambassadors can deepen engagement and strengthen trust. Furthermore, recognizing the extended social and familial implications of these conditions reinforces the human-centric approach of the study.

The Competitive Advantage of a Human-Centric Approach

Placing participant experience, engagement, and retention at the forefront has become a strategic necessity for the success of clinical trials. By adopting participant-centered strategies and utilizing advanced technological tools, sponsors and researchers can design studies that accommodate participants' needs, reduce burdens, and build enduring collaborations. This methodology not only enhances outcomes but also distinguishes sponsors within an increasingly competitive research environment.

Balancing Technology and Humanity in Clinical Trials

Michal Kouril, director, Strategic Solutions & Partnership, EMEA



Healthcare is undergoing a profound transformation, and participant experience and engagement stand at the forefront of both clinical research and care delivery. The integration of advanced technologies, such as artificial intelligence (AI), digital platforms, and remote monitoring solutions, is unquestionably transforming access, convenience, and operational efficiency within clinical trials. However, despite these advancements, the irreplaceable value of human connection remains vital.

Participants consistently express a need for genuine, empathetic interactions with clinicians, study coordinators, and research staff, especially as clinical trial protocols become increasingly complex and demanding. Cultivating meaningful relationships and trust with participants not only enhances recruitment and retention but also promotes higher levels of satisfaction, adherence, and data integrity.

This reinforces the pivotal role of the human element in successful and impactful clinical research.

Human interaction fosters trust, reduces anxiety, and enhances overall understanding of clinical research studies. It allows participants to share concerns, preferences, and feedback in ways that go beyond the capabilities of algorithms and automated systems. As technology facilitates personalized care, human touch provides reassurance and advocacy that technologies alone cannot offer. While AI and technology support, inform, and empower, it is the human connection that creates lasting engagement and satisfaction.

Organizations that prioritize and strategically optimize the human element of clinical trials gain a significant and sustainable competitive advantage. By placing participant experience, diversity, and engagement at the forefront, these organizations are well-positioned to recruit and retain a broad spectrum of study participants, reflecting the real-world populations that research aims to serve. By fostering genuine relationships and trust within communities, they enhance the credibility and impact of their research, drive superior trial outcomes, and ultimately contribute to advancing both scientific innovation and public health.

RELATED RESOURCES

- **PODCAST:** Health Literacy in Action: The Impact of Plain Language Communication in Clinical Research
- **REPORT:** A Centralized Approach to Clinical Trial Recruitment and Retention
- **REPORT:** Connecting the Dots: How Each Step in a Clinical Trial Fuels the Next

Cell and Gene and Advanced Therapies

Advanced therapies, encompassing cell, gene, and other transformative modalities, are rapidly maturing from promise to delivery. According to WCG ClinSphere® data, as of late 2025 there are more than 3,600 active and planned Cell and Gene and Advanced Therapies (CGT) trials globally, with 66% of those trials in oncology. As the pipeline for these therapies expands, the clinical trial ecosystem must adapt to their unique characteristics: complex manufacturing, individualized products, long-term follow-up, and heightened safety monitoring.

Within this dynamic, the notion of advanced therapies is no longer niche but central to innovation. For sponsors and sites alike, readiness means more than executing a standard protocol; it means aligning on logistics (e.g., chain of identity/chain of custody), regulatory frameworks, biomarker and genomic screening, and patient-centered design for often small, high-stakes populations.

Moreover, the shift toward these modalities intensifies pressure on operational agility: few participants, high cost, and the potential for life-changing outcomes put a premium on trial design and data inference. In the coming year, the focus will sharpen on optimizing site-investigator networks that are cell and gene therapy competent, enhancing supply chain robustness, and scaling hybrid models where appropriate. The ability to integrate advanced therapies into a seamlessly functioning trial infrastructure will separate successful programs from those delayed or compromised.

Cell and Gene Therapy: Advancing from Experimental Innovation to Clinical Mainstream

Sharad Adekar, MD, PhD, CIP, medical chair lead, IRB Operations

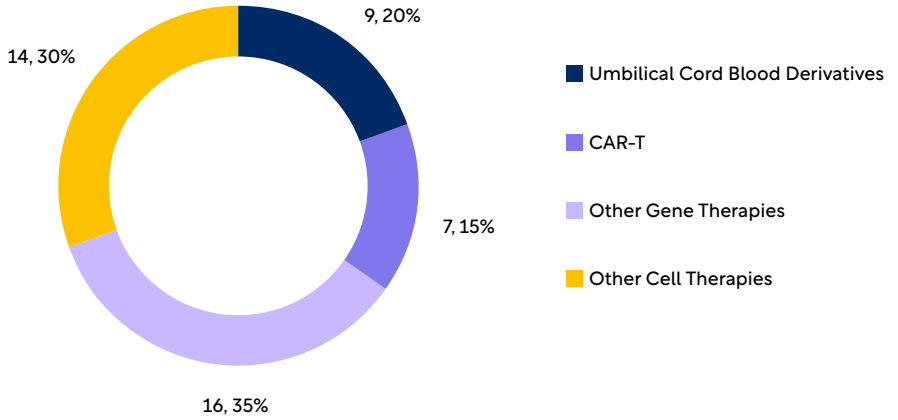


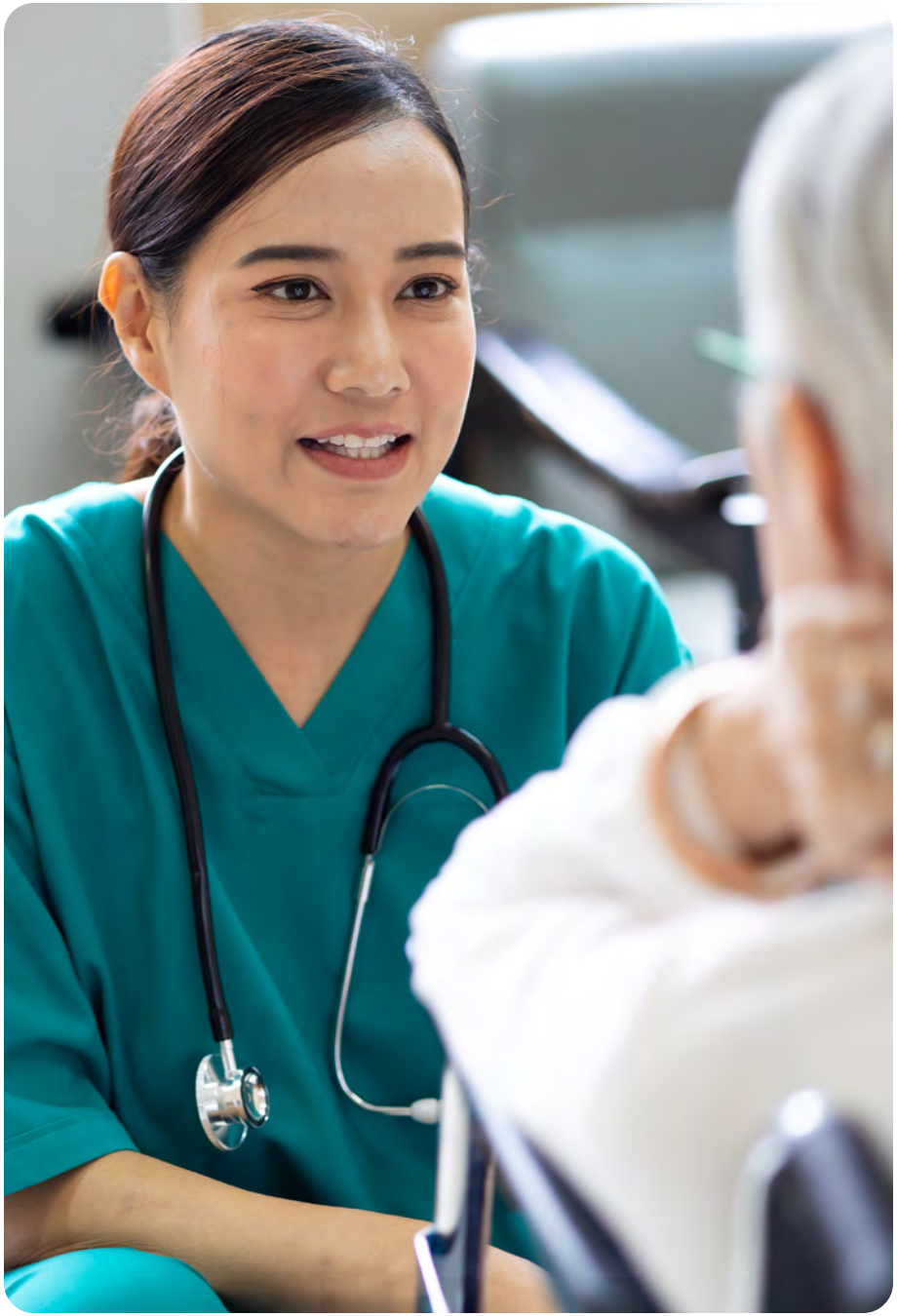
Figure 1: FDA-Approved Cell and Gene Therapy Products by Category
Currently, there are 46 FDA-approved cell and gene therapy products, which are presented by category in number and percentage.

Cell and gene therapies (CGT) have experienced significant advancement over the past decade, evolving from experimental concepts in research laboratories to established modalities in clinical practice[1]. These innovative therapeutics now stand at the forefront of medicine, providing promising, often curative options for patients with complex and previously untreatable conditions, including cancer, inherited disorders, and immune-related diseases. This progression has been driven by advances in biotechnology, genomics, and immunology. Technologies such as CAR-T cell therapy, gene editing with CRISPR, and stem cell-based interventions have moved from laboratory settings into real-world clinical applications[2].

As of late 2025, there are 46 FDA-approved therapies, classified into four main categories: umbilical cord blood derivatives, CAR-T therapies, other gene therapies, and other cell therapies (Figure 1)[3]. This regulatory momentum reflects a widening acceptance and integration into routine care, with products targeting a diverse array of diseases.

Operational Challenges in Clinical Trials

Despite these breakthroughs, the operational aspects of clinical trials for CGTs remain a bottleneck. Traditional trial site models frequently lack the necessary infrastructure to support the complex logistics inherent to advanced



CGTs. These therapies require comprehensive protocols for handling, storage, engineering, manufacturing, transportation, and administration of CGTs, as well as long-term follow-up and biosafety measures for participants and their close contacts. Additionally, the involvement of multidisciplinary teams is essential for early detection and effective management of adverse events, thereby ensuring safety and efficacy. Coordination among clinical sites, manufacturing facilities, and healthcare providers is more complicated when therapies are patient-specific and time-sensitive. Furthermore, gaps in workforce expertise and preparedness may affect trial efficiency, highlighting the need for specialized training and professional development.

Bridging Workforce and Readiness Gaps

The rapid expansion of CGTs has exposed significant gaps in workforce readiness. Many healthcare professionals are unfamiliar with these therapies, making comprehensive education and training essential. As CGT trials draw on multiple disciplines, teams must collaborate across genetics, immunology, pharmacology, and bioinformatics to ensure trial success.

To address these challenges, industry stakeholders should invest in infrastructure development, educational initiatives, certification programs, and partnerships with academic institutions to equip staff with the knowledge and skills required to handle the unique challenges associated

with CGTs, including patient selection, informed consent, treatment administration, adverse event monitoring, and post-treatment follow-up.

Expanding Therapeutics Horizons Beyond Oncology

While oncology has been the primary focus of CGTs' development, the field is now branching into other therapeutic areas. Neurology, ophthalmology, cardiology, and rare genetic disorders are emerging as promising targets for advanced therapeutics. This diversification underscores the versatility of CGT platforms and their potential to transform the treatment landscape for a wide range of diseases.

Looking Ahead: Building a Sustainable Future for Advanced Therapeutics

As CGTs transition into mainstream therapeutic options, it is imperative for the healthcare system to address operational, regulatory, and workforce-related challenges to fully realize their benefits. By updating clinical site models, adapting regulatory frameworks, and investing in workforce development, the field can offer transformative, personalized treatments and firmly establish CGTs as a cornerstone of future medicine.

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New Ways to Develop Personalized Genetic Medicines for Rare Disease

Daniel Kavanagh, PhD, RAC, senior scientific advisor, Gene Therapy, Vaccines & Biologics

Of the more than 10,000 types of rare diseases, around 80% have a genetic cause, presenting a broad range of opportunities to address unmet medical needs through gene therapy and interventional genomics. In 2025, an important advance was made with the successful treatment of "Baby KJ" using a bespoke gene editing product, manufactured at unprecedented speed to treat an inborn error of metabolism.

The clinical intervention in the Baby KJ case was remarkable as both a technical clinical advance and a trailblazing event toward potential new regulatory pathways. Baby KJ was born with mutations in both copies of the CPS1 gene on Chromosome 2. Mutations in this gene can cause carbamoyl phosphate synthetase I deficiency, a rare disorder that leads to ammonia toxicity and neurological damage.

Through heroic efforts, investigators developed a liver-targeted, lipid nanoparticle (LNP)-delivered gene editing product for clinical administration within a few months of diagnosis. After a series of treatments with this investigational product, Baby KJ showed significant and progressive clinical improvements with no major adverse events reported to date.

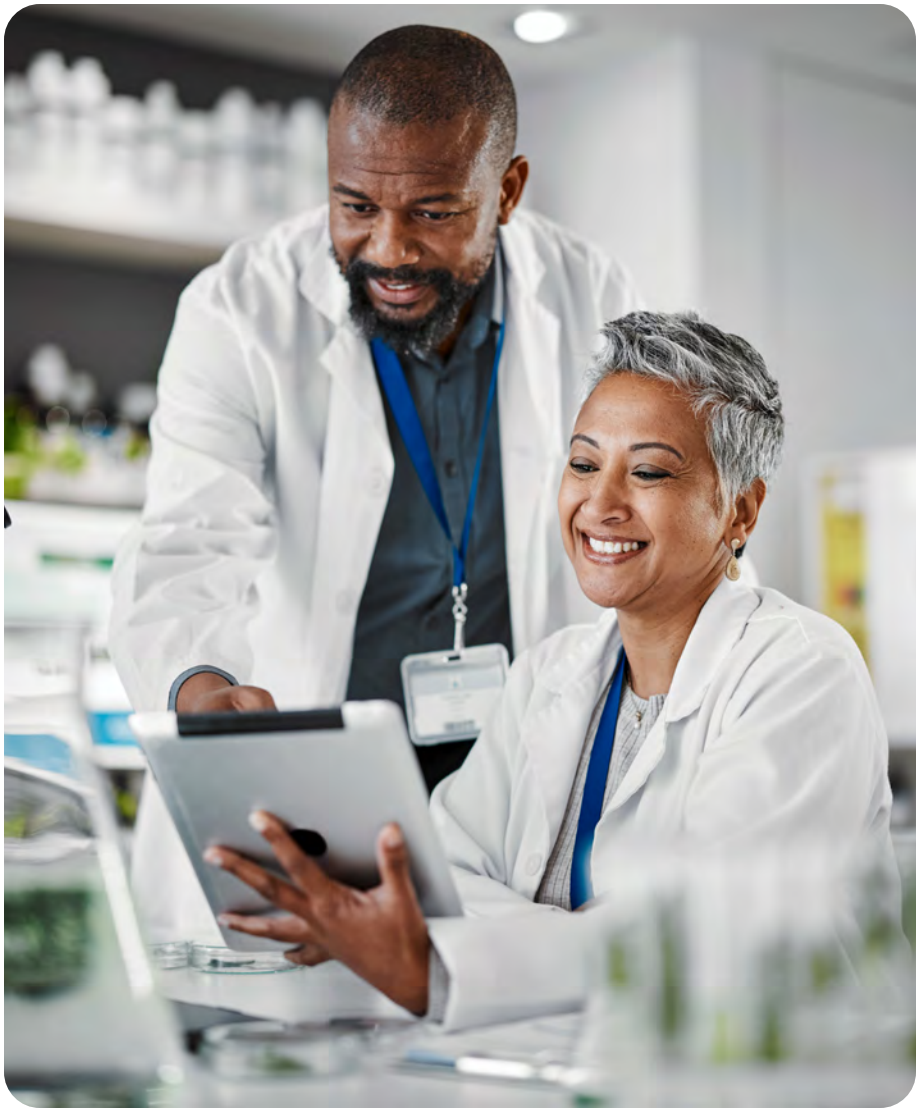
Historically, the development of genetic therapies for ultra-rare disease has been hampered by a need to "reinvent the wheel" with respect to preclinical testing and CMC (Chemistry, Manufacturing, and Controls) considerations. Another challenge relates to the requirement to develop "substantial evidence" of safety and efficacy in support of Biologics License Application (BLA) marketing approval.

Evidence in this realm is traditionally developed through randomized controlled clinical trials, which are logistically difficult or impossible for rare and ultra-rare diseases.

In recent years, FDA, NIH, and gene therapy leaders from industry and academia have made significant progress toward the development of platform-based approaches to gene therapy. In May 2025 the Accelerating Medicines Partnership of the Foundation for the National Institutes of Health (FNIH) released the a fully digitized version of their Bespoke Gene Therapy Consortium (BGTC) Regulatory Playbook (BGTC Regulatory Playbook), intended to support adeno-associated virus (AAV) gene therapy drug developers, with an emphasis on therapeutic platforms that allow multiple related development platforms to move forward while minimizing superfluous or duplicative efforts.

For some inherited diseases, gene editing and interventional genetics approaches, like those used with Baby KJ, are more suitable than AAV therapies. In late 2025, lead investigators from that project published a description of their productive pre-IND work developing interventional genetics platforms for selected therapeutic areas (How to create personalized gene editing platforms: Next steps toward interventional genetics - ScienceDirect).

Shortly thereafter, FDA leaders published a description of a planned new "Plausible Mechanism" pathway for marketing approvals of drug products meeting specific criteria with respect to medical need and supporting data (FDA's New Plausible Mechanism Pathway | New England Journal of Medicine). In combination, these technical and regulatory advances indicate an opportunity for rapid acceleration of genetic medicines for rare diseases in 2026 and beyond.



Tokenization to Leverage Real-World Clinical Data for Long-Term Follow-Up

Kelly FitzGerald, PhD, executive IRB chair & vice president of IBC Affairs, IRB Operations

Daniel Kavanagh, PhD, RAC, senior scientific advisor, Gene Therapy, Vaccines & Biologics

Long-term follow-up — the extended monitoring of participants beyond the initial investigational treatment period — is a critical part of many drug development programs, including certain applications in oncology, vaccines, transplants, and pediatric diseases. Notably, a long-term follow-up plan is required for all FDA-regulated gene therapy trials.

Some long-term follow-up studies may require frequent research-related clinical visits, testing, and procedures, which involve significant costs and can be burdensome to participants, resulting in loss of follow-up.

To reduce these burdens, the FDA published draft guidance in 2025 supporting the growing use of real-world data (RWD) to help assess the long-term risks and benefits of gene therapy products. Examples of relevant RWD include electronic health records, claims and billing data, patient registries, and pharmacy records.

The use of Privacy-Preserving Record Linkage (PPRL) approaches, such as tokenization, promotes efficient analysis of relevant data from disparate sources without revealing Personally Identifiable Information (PII). Tokenization uses an irreversible cryptographic process to link health records to an anonymized secure "token" representing a clinical trial participant.

Implementing PPRL technologies requires careful attention to ethical oversight and informed consent. To understand the prevalence of tokenization in greater-than-minimal-risk protocols under WCG review, in May 2025 we searched all protocols reviewed in convened meetings to identify references to data tokenization within the preceding 12 months (Table 1, page 42). We found no history of deferrals or conditional approvals, indicating that ethical issues were generally well addressed in submitted protocols.

The Institutional Review Board (IRB) considers the following criteria for approval: that risks are minimized,

	Total New Protocols Reviewed	Protocols Using Tokens	Deferrals & Conditional Approvals for Tokens
May 2024 – May 2025	~3000	21	0

Table 1: Data Tokenization

the risk-benefit ratio is reasonable, and there are adequate provisions for the confidentiality of data and the protection of participant privacy. Members of the IRB consider potential physical, psychological, social, legal, and economic harm.

At a minimum, when there is a possibility of using data for future research, the consent form should include a statement that identifiers might be removed from the identifiable private information and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent. Studies involving tokenization should also reference the linking of study data to future unspecified datasets and clarify that additional consent will not be sought.

We expect that PPRL technologies, tokenization, and real-world data will be leveraged in an increasing number of studies in 2026 to minimize participant burdens and enhance the value of long-term follow-up.

RELATED RESOURCES

- **BLOG:** Best Practices for Protecting Non-Participants in Human Gene Transfer Clinical Trials
- **WEBINAR:** Beyond the Trial: Ethical Oversight in Gene Therapy Long-Term Follow-Up

Bringing the Future into Focus

As the clinical research industry enters 2026, the themes reflected across these insights converge on a single, defining reality: progress will be determined not only by scientific innovation, but by the industry's ability to operationalize that innovation responsibly, collaboratively, and with resilience. Artificial intelligence is rapidly becoming embedded across the trial lifecycle, offering new ways to predict, streamline, and support decision making. Yet its power depends on the strength of the governance, transparency, and oversight we bring to it.

At the same time, clinical research sites stand at the center of both challenge and opportunity. Their readiness, capacity, and operational maturity will shape the speed and quality with which novel therapies reach patients. Strengthening site infrastructure, reducing unnecessary capacity, and fostering deeper alignment between sponsors, sites, and CROs are no longer optional; they are essential to keeping pace with scientific advancement.

Across every trend, the experience of participants remains the constant thread. As expectations rise and burdens increase, organizations that commit to participant-driven design, equitable compensation, and meaningful human connection will distinguish themselves. Technology can improve access and efficiency, but trust, clarity, and empathy will continue to define the participant journey.

The emergence of advanced therapies, particularly cell and gene modalities, further underscores the need for readiness. These therapies promise profound benefit but demand precision, specialized expertise, and a coordinated ecosystem capable of supporting their complexity.

Taken together, these signals point to a year in which clinical research becomes more interconnected than ever. Success in 2026 will hinge on how well we integrate technology with judgment, innovation with ethics, and efficiency with humanity. As the industry moves forward, those who embrace this balance will set the pace for a more agile, equitable, and impactful era of clinical research.

WCG is at the forefront of accelerating clinical research worldwide, serving as the trusted and preferred partner to biopharmaceutical and medical device companies, contract research organizations (CROs), research institutions, and site partners. Offering a unique combination of expertise, next-generation data and insights, and tech-enabled solutions, WCG reduces complexity and optimizes study operations and outcomes while maintaining the highest standards of human participant protection. For more than 55 years, WCG has maintained a relentless commitment to efficiency, safety, and impact, empowering clinical trials to deliver life-improving therapies swiftly. For more information, please visit wcgclinical.com or follow us on LinkedIn.

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